SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

SEPTEMBER 25, 2015

The Committee met by teleconference on Friday, September 25, 2015, at 11:00 am EST. Chair Shawn Kassner led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (Other)	Present
Kareen Baker, Independent (Other)	Present
Nicole Cairns, NYSDOH (Other)	Present
Rachel Ellis, NJ DEP (AB)	Absent
Scott Hoatson, Oregon DEQ (AB)	Present
Shawn Kassner, Phenova (Chair; Other)	Present
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Absent
Mitzi Miller, Dade Moeller Assocs. (Other)	Present
Judy Morgan, Pace (Lab)	Present
Joe Pardue, P2S (Vice-Chair; Other)	Present
Jim Todaro, Alpha Analytical (Lab)	Absent
Lisa Touet, MA DEP (AB)	Present
Ken Jackson, Program Administrator	Absent

Associate Committee Members present: Mike Blades, ERA; Amanda Bruggeman, Phenova; Audrey Cornell, ERA; Craig Huff, ERA; Tim Miller, Phenova; Bob O'Brien, Sigma-Aldrich; Brian Stringer, ERA.

2 – Previous Minutes

It was moved by Scott and seconded by Fred to approve the minutes of September 11, 2015. All were in favor except Lisa who abstained.

3 – Updates

Shawn had gathered all the requests for Committee Membership and had sent them e-mails to check they are still interested. He said he would then schedule a Members'only meeting to decide who to appoint.

4 – Comments on V3 Voting Draft Standard

Shawn said every time the committee worked on the Volume 3 comments he would make the agreed changes to the volume and then send it out for everyone to see before the next meeting.

Comments considered by Lisa.

5.6.3.6 "*Some additional wording may be needed to make the requirements unambiguously clear.*

Recommended language after changes are made: PT samples or analytes which fail to meet the criteria of this Section shall be invalidated in the PT study (scheduled or supplemental) and

described in the study discussion report." Lisa's drafted response: Non-persuasive-This section describes stability testing and the need to invalidate PT samples or analytes in the event that stability requirements are not met. Section 5.4.3.1b indicates that stability requirements also apply to supplemental studies. Supplemental PT samples are a subgroup of PT samples in general, therefore the stability requirements would be applicable to both types of studies, without specifically stating such. No other section includes the parenthetical information. To include it here would be inconsistent with the remainder of the document. Others agreed with this response. Nicole moved and Joe seconded this comment should be considered non-persuasive. All were in favor.

5.7.3 "*The whole section is not clear as to what the contingencies are and the requirements for each case. Recommended language after changes are made: 5.7.3 Assigned values for quantitative microbiology and protozoan analytes:*
(a) shall be equal to the study calculated mean as specified in Sections 5.9.2.5 or 5.9.2.8,. as appropriate, and either:
(b) shall be presented as a whole number with no more than three (3) significant figures for quantitative methods utilizing microbial colony counting techniques; (for example, membrane filtration methods (MF) and pour plate methods), or
(c) shall be set to three (3) significant figures for quantitative methods utilizing statistical probability techniques; (for example, most probable number (MPN) methods)." Lisa felt adding the either/or and parentheses provides clarification, and she recommended adopting the suggested language. Nicole said these changes would be inconsistent with other sections (e.g., WET) that have similar wording. Others thought the text was already clear, and Shawn suggested it should be non-persuasive to retain the consistency. Nicole moved and Joe seconded this comment should be considered non-persuasive. All were in favor.

5.9.2.8 "*The section delineating 5.9.2.8.1 is not needed, since there is no clause 5.9.2.8.2. For clarity, please delete "5.9.2.8.1" and place this sentence as the second sentence in the main clause for 5.9.2.8."* It was agreed this change should be made, and it would be editorial.

5.9.2.8.1 "*Why is this limited to the accredited laboratories? The evaluation of the PT results will be the same whether or not the laboratory is TNI accredited. Possible Resolution: Remove the term "accredited.""* Lisa agreed, saying PT vendors would not know whether a participant was accredited. It was moved by Fred and seconded by Scott to accept the proposed change.

5.6.4.2. "*Redundant with clause 4.5 of this standard. Possible Resolution: Combine requirements in 4.5. Possible Language: 4.5 PT providers shall submit data on the assigned value verification, homogeneity, and stability testing for all PT samples/analytes included in each of their TNI EL V3 PTPAccredited PT studies to the PTPA for review to determine compliance with this Standard."* Lisa had considered the comment persuasive, because the section requires the provider to release specific types of study data to the PTPA after the issuance of final reports. Section 4.5 requires the PT provider to submit data to the PTPA to document compliance with the standard. It is more general and 4.5.1 states that the PTPA determines the information required. She had recommended that 5.6.4.2 be removed. Scott, however, argued each section pertains to a different purpose for reporting, so the language should remain. On further discussion, others agreed with Scott. It was moved by Fred and seconded by Judy to rule the comment non-persuasive and to leave both sections in the standard. All were in favor.

Comments considered by Fred.

5.9.3.3 "*In the second paragraph the acronym PTP appears without any clear definition of what this stands for. Also, a comma needs to be inserted for clarity to separate the dependent clause from the independent clause. Recommended language for the second paragraph of Clause 5.9.3.3 after changes are made: If an analyte in the PT sample is invalidated, the reported value shall be scored "No evaluation" and the PT provider ~~PTP~~ shall provide an explanation of the cause for invalidation in the final evaluation report …"* Fred suggested accepting the proposed change, since the acronym "PTP" was not defined. This was accepted as an editorial correction.

5.10.1.3 "*Section header 11.2 (Final Evaluation Report) was crossed-out in the VDS. It should be restored for clarity, since the preceding section header (Schedule) is still present, and the sections subsequent to 5.10.1.2 do not involve scheduling. Possible Resolution: Restore section 11.2 (Final Evaluation Report) and renumber as 5.10.2. Renumber subsequent sections 5.10.1.3, 5.10.1.4, and 5.10.1.5 to section numbers 5.10.2.1, 5.10.2.2, and 5.10.2.3, respectively. Renumber Section 5.11 (Study Failure Rate Report) to 5.10.3, and the subsequent section to 5.10.3.1."* Fred agreed this could be renumbered as suggested. The committee accepted this was an editorial correction.

5.10.1.3 (g) "*I was not aware that EPA accredits laboratories or assigns an accreditation number. It is not clear if EPA is assigning any numbers at all to brand-new laboratories. Recommended change: Change Subsection (g) to read: "EPA laboratory ID ~~accreditation~~ number, if known;""* It was agreed the comment was correct and this was deemed an editorial correction.

5.10.1.4 (e) A typographical error was corrected editorially

5.10.1.3 "*I would like to suggest analyst be added to the list. Having the analyst name/initials provides traceability to the samples analysis records for the PTs."* Fred felt this could be done, and it would be a good first step to at least add the name of the person performing the analytical measurement step. Shawn added there is no requirement in V1M1 to record that information. Mitzi argued it would be difficult when separate people do the preparative and analysis steps, and where there are workgroups. She also said it would be inappropriate to publicly identify the individual, since it is the laboratory that bears the responsibility for its work. It was moved by Mitzi and seconded by Fred that it is non-persuasive because it is not required in Volume 1 and it is information the laboratory should maintain, and it is not essential to the report. All were in favor.

5.10.4 "*V4 adds requirements (Sections 5.4.3 and 5.4.4) for the PTPA to ensure the PTP is able to (and does) provide data upload to TNI per PTPEC request. There needs to be a corresponding requirement in V3 to require the PTPs to provide this data. Possible Resolution: Add Section 5.10.4 (after renumbering per my preceding comment), "PT Study Data Submission", and Section 5.10.4.1: "Upon request of the PTPEC, the PT Provider shall make available, via electronic upload to TNI, such PT Study data as PTPEC may require. The format and specifications of this electronic upload shall comply with requirements defined by PTPEC.""* Shawn was concerned this was a very broad requirement that would leave the PTPEC able to request any information it wanted from PTPs. PT Providers on the call said they would want to know what information could be requested. Nicole said all requests for information should go through the PTPA and should not be reported directly to TNI. Scott was concerned about a disconnect with the Volume 4 requirement, and he suggested addressing this item in Volume 4 at the same time to make that more specific. Shawn said there had been a meeting between the PTPs and PTPAs, and he would ask Maria Friedman the outcome on the issue. Meanwhile, he would label the comment Non-Persuasive.

Comments considered by Scott.

4.5.2 "*This violates the requirements documents of the ILAC AB, ISO/IEC 17011 and the contractual obligations of the PTP. By standard, requirements documents and contract all relevant aspects both documents and records of the PTP are subject to review by the PTPA. This sets precedent for the PTP to cherry pick what records are reviewed, a PTP can claim, a record has a client ID on it therefore cannot be reviewed. OF the most simple examples, how would an AB review conformance to the requirements relating to a final report? The employees and contracted assessors sign confidentiality agreements to the AB and reaffirm them regularly, as well as provide a signed agreements to the customer at the time of assessment. Aspects related to confidentiality are reviewed at both the opening and closing meetings as well."* There was a protracted discussion. Scott pointed out once PT results have been released to a state they are a matter of public record anyway. Nicole read out relevant clauses from ISO 17043, which says if data are to be released, the participants have to be notified in advance (though it does not say the participants have to give permission). Shawn agreed this was redundant with ISO 17043, but he disagreed it violates ISO 17011. It was moved by Nicole and seconded by Judy that the comment is persuasive because of redundancy with ISO 17043. All were in favor.

5 – Next Steps

At the next meeting, the committee would continue with the Volume 3 comments. In the meantime the verification/homogeneity subcommittee would be reinstated. Shawn would ask Maria Friedman to join the next call on October 9 to address the issue concerning clause 5.10.4.

Adjournment

The meeting was adjourned at 12:30 pm EDT.